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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,138	02/02/2004	Paul John Rennie	9510	9660

27752 7590 01/04/2007

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/770,138	RENNIE ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/05, 6/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The treatment of SARS is not disclosed in the prior-filed application 09/692,634 or 09/421,131 and therefore has an effective filling date of 02/02/2004. The respiratory tract composition is not disclosed in the prior-filed application 09/421,131, but is disclosed in the 09/692,634 application, thus the effective filling date for the composition is 10/19/2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to treat SARS, does not reasonably

provide enablement for a method to prevent SARS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of treating and preventing SARS by administering a respiratory tract composition. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 1 is drawn to " a method of preventing and treating SARS by administering a respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: (a) from about 0.001% to about 20% by weight of an organic acid; and (b) from about 0.01% to about 20% by weight of a metal compound."

(2) The breadth of the claims:

Claim 1 embraces and reads on preventing SARS by administering a respiratory tract composition. The specification does not enable the prevention of SARS by administering a respiratory tract composition.

(3) The state of the prior art:

The state of the art regarding preventing SARS is very low or do not exist.

(4) The predictability or unpredictability of the art:

The predictability of preventing SARS is relatively low. Therefore, to one skilled in the art, prevention of SARS is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the prevention of SARS by administering a respiratory tract composition is completely lacking. The specification states that the composition alleviated symptoms associated with SARS and prevented the reoccurrence of virus symptoms (see specification, page 16, lines 7-10). This example is does not demonstrate the prevention of SARS because the patient

already was infected SARS. The patient would need to not be infected with SARS and then data showing that the patient was never infected with SARS after receiving the respiratory tract composition. The specification as filed does not speak on or show any working examples any studies performed that prevent SARS, especially by administering a respiratory tract composition. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2194.

(7) The quantity of experimentation necessary:

The instant claims read on the prevention of SARS. As discussed above the specification fails to provide any support for completely preventing SARS. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for a method for treating SARS, but not for the prevention of SARS.

The claims are examined on the merits for a method of treating SARS and the prevention of SARS.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 1-5 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601).

Gelber et al. teaches a method and composition that treats a condition caused by an immune response to a virus (see abstract, lines 1, 5-6, and 13-15) and respiratory system (see page 5, paragraph 56, lines 2-3). The aqueous saline solution of the composition can be applied by a spray, which is administered onto the nasal mucosa (see page 7, paragraph 69, lines 8-10; addresses applicant's claims 11-15). Preferred ingredients for the formulation include zinc acetate, zinc gluconate, zinc oxide, citric acid (see page 5, table 3; addresses applicant's claims 1 in part and 3-5), and ascorbic acid (see page 2, paragraph 13, column 2, line 1 and page 3, paragraph 31, line 15;

addresses applicant's claim 1 in part). In regards to the pH of the composition, it is inherent that the composition have a pH from about 3.0 to about 5.5 because Gelber et al. teaches a composition comprising ascorbic acid, which has a pH of about 3. Zinc gluconate is administered in the range of approximately 0.1 mg to 15mg (see page 9, paragraph 73, line 30; addresses applicant's claim 1 in part) or 2.5 mg to 30 mg (see page 10, paragraph 85, lines 8-9). Ascorbic acid is administered in the range of approximately 50 mg to 1000 mg (see page 9, paragraph 73, line 33; addresses applicant's claim 1 in part).

Gelber et al. does not specifically teach a method of treating SARS.

Adams et al. teaches a method of stimulating an immune response of a viral infection (see claim 134) such as a SARS infection (see claim 137; addresses applicant's claim 1 in part). The administration of the method may be delivered in the form of an aerosol spray (see page 40, paragraph 361, line 3) mucosally (see page 40, paragraph 364, line 2) to the nose (see page 41, line 8).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Gelber et al. with a method to treat SARS is because (1) Adams et al. teaches a method of treating a viral infection, particularly SARS with a nasal spray composition and (2) Gelber et al. teaches compositions to treat viral infections that are respiratory infections.

The motivation to combine a method of Gelber et al. with a method to treat SARS is because Gelber et al. teaches compositions to treat viral infections, particularly respiratory infections (i.e. influenza). Thus, since SARS is a respiratory infection caused by a virus, and Gleber et al. (see abstract, lines 5-6 and see page 5, paragraph 56, lines 2-3) compositions and methods treat viral infections, particularly respiratory infections, then the compositions of Gleber et al. would treat SARS.

(2) Claims 6-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1), in view of Adams et al. (US 2004/0077601) as applied to claims 1-5 and 11-15 above and in further view of Kamishita et al. (5,158,761).

The teachings of Gelber et al. and Adams et al. are as applied to claims 1-5 and 11-15 above.

Gelber et al. and Adams et al. does not teach a composition comprising a mucoadhesive polymer (applicant's claim 6 and 8), a viscosity of from about 1 cps to about 2000 cps (applicant's claim 7), or a pH adjusting agent (applicant's claim 10).

Kamishita et al. teaches a spray base gel composition comprising an aqueous solution of carboxyvinyl polymer with a water-soluble basic substance with a viscosity within the range of 500-5,000 cps (see abstract; lines 1, and 3-6; addresses applicant's claims 1, 6, 12-14 in part). A pH value of the spray gel is adjusted to the desired pH with a water-soluble basic substance such as sodium hydroxide (see column 3, lines 40 and 42) or other pH adjustors taking into consideration the stability or absorption of an active medicament (see column 4, lines 25-29; addresses applicant's claim 10). In order to improve the spread-stick property in sprays of an aqueous solution and increase the viscosity, generally thickeners such as hydroxypropyl cellulose, hydroxypropyl methylcellulose and polyvinylpyrrolidone (PVP) are used (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6; addresses applicant's claims 6 and 8). The pH of the composition rages from 4-9 (see claim 1, line 3; addresses applicant's claim 1 in part). The preparation is applied to mucous membranes in the nasal cavity (see column 6, lines 47-50; addresses applicant's claims 11-13 and 15). The preparation is useful in a clinical use, like an influenza vaccine (see column 6, lines 11-13).

To one of ordinary skill in the art it would be obvious to combine the composition of Gleber et al. and Adams et al. with a mucoadhesive polymer, a viscosity of from about 1 cps to about 2000 cps, and a pH adjusting agent is because (1) both Kamishita et al. and Gleber et al. teach aqueous, nasal spray respiratory anti-viral compositions and methods that are applied to the nasal mucosal tissue; and (2) Kamishita et al.

teaches a composition having a pH of 4-7 (see claim 1, line 3) with a viscosity of 500-5,000 cps (see claim 1, line 3), comprising hydroxypropyl cellulose or hydroxymethyl cellulose (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6), and the pH adjuster sodium hydroxide see column 3, lines 40 and 42).

The motivation to combine a composition of Gelber et al. and Adams et al. with a mucoadhesive polymer, a pH adjustor, and a viscosity of from about 1 cps to about 2000 cps is because Kamishita et al. teaches a composition comprising a mucoadhesive polymer (i.e. carboxyvinyl polymers, hydroxypropyl cellulose, hydroxypropyl methylcellulose and polyvinylpyrrolidone; see abstract, line 3; column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6), a pH adjustor (i.e sodium hydroxide; see column 3, lines 40 and 42) and wherein the composition has a viscosity within the range of 500-5000 cp so that (1) the particle size distribution of the spray after spraying is 80% in the area of 20-100 μm (see column 3, lines 10-16), (2) the spead-stick property of the spray may be effective (see column 1, lines 59-62), and (3) to keep in consideration the stability or absorption of an active medicament (see column 4, lines 25-29). Thus, having a composition comprising a mucoadhesive polymer, a pH adjustor, and a viscosity of from about 1 cps to about 2000 cps would increase the efficacy of the spray to treat SARS by providing excellent spray base properties (see column 2, lines 40-45). A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff,

919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

(3) Claim 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601), in further view of Kamishita et al. (5,158,761), as applied to claims 1-8 and 10-15 above and in further view of Betbeder et al. (6,017,513).

Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601), and in further view of Kamishita et al. (5,158,761), teachings are as applied to claims 1-8 and 10-15 above.

Gelber et al., Adams et al., and Kamishita et al. do not teach a composition comprising the mucoadhesive polymer as a thermoreversible polymer selected from the

group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof (applicant's claim 9).

Betbeder et al. teaches the use of an amphiphilic compound such as poloaxamers, modified polyoxyethylene and other surface active compounds (see column 7, lines 22-23) for the use in a nasal (see column 4, line 45) mucosal administration (see abstract line 1) to reduce the effect of a virus infection (see column 8, lines 33-34, 38 and 47-48).

To one of ordinary skill in the art at the time of the invention, it would be obvious to combine the method and compositions of Gelber et al., Adams et. al., and Kamishita et al. with the mucoadhesive polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses and mixtures thereof is because (1) Kamishita et al. teaches the use of the mucoadhesive polymers hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone (PVP) (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6), and carboxyvinyl polymers (see abstract; line 1) in a nasal mucosal composition to treat viral infections (see column 6, lines 47-50); (2) poloxamers, ethylhydroxy ethylcelluloses, PVP, carboxyvinyl polymers, PVP and hydroxypropyl methylcellulose are all mucoadhesive polymers; and (3) mucoadhesive polymers are known within the art to be used in nasal compositions.

The motivation to combine the method and compositions of Gelber et al , Adams et. al., and Kamishita et al. with the mucoadhesive polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses and mixtures thereof is because mucoadhesive polymers are known within the art to be used in nasal compositions as shown by Kamishita et al. Additionally, Betbeder et al. demonstrates that the specific poloaxamer is used to confer a physico-chemical environment appropriate to the substance, the mode of mucosal administration, and the desired effect (see column 7, lines 1-3). Thus, one skilled in the art would be able to choose the appropriate mucoadhesive polymer for the composition, since they are commonly used in nasal compositions.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER